K060520
Page 1 of 1

MAR 2 8 2006

SECTION 1 510(k) Summary

SUBMITTED FOR:

Company Name: Proxy Biomedical, Ltd.
Address: Unit 6D, Mervue Business Park
Galway, IRELAND
Contact Person: Peter Mulrooney, Quality Assurance Manager
Tel: +353 (0)91 709161 Fax: +353 (0)91 709162

Submitted by: Elaine Duncan, M.S.M.E., RAC
President, Paladin Medical, Inc.
PO Box 560
Stillwater, MN 55082
715-549-6035
715-549-5380

CONTACT PERSON: Elaine Duncan
DATE PREPARED: Feb 11, 2006
TRADE NAME: VITAMESH™
COMMON NAME: Surgical Mesh
REGULATORY CLASS: This device is class II
DEVICE PANEL AND PRODUCT CODE: General and Plastic Surgery
21 CFR 878.330 FTL

SUBSTANTIALLY EQUIVALENT TO: VITAMESH™ is substantially equivalent to the Bard PTFE Mesh. (Davol Inc.),Mersilene Mesh (Ethicon, Inc.), and the Bard Mesh (C.R. Bard, Inc.) a polypropylene mesh.

DESCRIPTION of the DEVICE:
The VITAMESH ™ is a non-absorbable, synthetic mesh, constructed of knitted filaments of Polyproylene. The VITAMESH™ is supplied sterile and provided in sheet form to be cut to size and sutured by the surgeon to meet the patient's needs. The mesh is approximately 0.010" thick, and exhibits high burst strength and tensile strength. The VITAMESH™ is knitted by a process which provides for elasticity in both directions. Use of VITAMESH™ allows a fibroblastic response through the interstices of the implant, forming a strong fibrous wall.

INDICATIONS FOR USE:
Proxy Biomedical VITAMESH™ surgical mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

SUMMARY of TESTING:
Bench test data demonstrate that VITAMESH™ has mechanical and material characterization values that are substantially equivalent to the predicate devices. The biocompatibility test results show that the material used in the design and manufacture of the device is non-toxic and non-sensitizing to biological tissues consistent with their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 8 2006

Proxy Biomedical, Ltd.
c/o Paladin Medical, Inc.
Ms. Elaine Duncan, M.S.M.E., RAC
President
P.O. Box 560
Stillwater, Minnesota 55082

Re: K060520
Trade/Device Name: VITAMESH™ MacroPorous PP Surgical Mesh
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: FTL
Dated: February 23, 2006
Received: February 27, 2006

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115 Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K060520

Device Name: VITAMESH™ MacroPorous PP Surgical Mesh

Indications For Use:

Proxy Biomedical VITAMESH™ surgical mesh is intended to assist in the repair and/or reinforcement of hernia and other fascial defects requiring the additional support of a nonabsorbable implant during and after wound healing.

Prescription Use ____x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060520